Initial Approval: April11, 2018

CRITERIA FOR PRIOR AUTHORIZATION

Voretigene neparvovec-rzyl (Luxturna™)

PROVIDER GROUP Professional

MANUAL GUIDELINES All dosage forms of the following drugs require prior authorization:
Voretigene Neparvovec-rzyl (Luxturna™)

CRITERIA FOR PRIOR AUTHORIZATION: (must meet all of the following)

- Patient must have a diagnosis of retinal dystrophy
- The patient's retinal dystrophy must be associated with a biallelic RPE65 mutation, as confirmed by an FDA-approved test
    - Documentation of genetic testing confirming the presence of a bilallelic RPE65 mutation must be provided
- Patient must have sufficient viable retinal cells as determined by non-invasive means, such as optical coherence tomography (OCT) and/or ophthalmoscopy. Must have one of the following:
    - An area of retina within the posterior pole of >100 microns thickness (shown on OCT);
    - ≥3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole; or
    - Remaining visual field within 30◦ of fixation as measured by III4e isopter or equivalent
- Patient must be 1 year of age or older
- Must be prescribed by or in consultation with an ophthalmologist
- Patient has not received prior RPE65 gene therapy in intended eye
- If both eyes are to be treated, the initial eye's injection and the second eye's injection must be administered at least 6 days apart

LENGTH OF APPROVAL One time approval (1 injection per eye)

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR	PHARMACY PROGRAM MANAGER DIVISION OF HEALTH CARE FINANCE KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
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DATE	DATE